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⑤4発明の名称　超音波発振素子付き薬物注入具

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明　　細　　書

1.発明の名称　超音波発振素子付き薬物注入具

2.特許請求の範囲

1.　薬物等の供給部並びに超音波発振器又は超音波発振器と接続するコネクターを備えた基部の先端に超音波発振素子を備えた導管を接合し、この超音波発振素子と超音波発振器とを電気的に結合してなることを特徴とする超音波発振素子付き薬物注入具。

3.発明の詳細な説明

〔産業上の利用分野〕

本発明は、人体外からカテーテル又は薬物注入導管を介して薬物を体内に注入して注入部位に直接超音波振動を付与し、注入薬物等の拡散，浸透を良好にする薬物注入具に関するものである。

〔従来の技術〕

人の病気の治療，予防等に外部より薬物を投与する方法としては、注射剤，経口剤，座剤，経皮投与剤等による経口，非経口的に投与する方法がある。特に体内に直接薬物等を注入する方法としては、局所注射，動静脈注射，血管内カテーテル等を介して体内の目的部位に薬物を注入する方法がある。

これらの手段によって薬物を直接体内に注入する場合は、注入された薬物が体内の組織へ拡散，浸透しにくいものもあり、それを良好にするために従来は化学的な手法によるものが主であった。

本発明者は先にカテーテルによる薬物投与の際、薬物の拡散，浸透を良くするため超音波を用いることに着目し、カテーテルに接続している基部より超音波による振動を与える血管洗浄器を発明した(特開昭56-52071号公報)。

〔発明が解決しようとする課題〕

本発明は上記従来の技術において、カテーテルによる薬物注入の場合、カテーテルにより血管内に注入された薬物の血管内留置物への拡散，浸透を良好にするため超音波を利用する方法においては、カテーテルの先端に超音波を伝達する際、超音波発振器が体外に有り、カテーテルの先端より遠い位置にあるため、途中での超音波エネルギー

の減衰があり充分な効果を発することは困難であった。

〔課題を解決するための手段〕

本発明者はカテーテルによる薬物等注入の際、血管内に注入された薬物等が血管内留置物への拡散，浸透を良好にするため超音波を利用する方法を更に研究を行った結果、超音波発振素子をカテーテルの体内挿入部の先端に付け、その発振線を体外に位置する基部に取付け、この発振線と発振素子を電気的に接合することによって、薬物の注入局所での拡散，浸透が極めて良好に行われることを見出し、更にこれをカテーテルのみならず、体内に挿入する器具に適用することによって、利用範囲の広い薬物注入器具を提供する本発明を完成した。

本発明は、薬物等の供給部並びに超音波発振機又は超音波発振線に接続するコネクターを備えた基部の先端に超音波発振素子を備えた導管を接合し、この超音波発振素子と超音波発振機とを電気的に接合してなる超音波発振素子付き薬物注入具である。

本発明に使用する先端に導管を接合した薬物注入具は、中央に薬物等の流通路並びに、その開放部を薬物等の供給口として有する基部、その基部の供給口の反対側の先端に、薬物等の流通路に対応する流通路を中央に有する金属，ゴム，プラスチックなどの中空細管で形成した導管を接合したもので、一般に胃，腸，食道，気管，血管などに使用する他、直接体の組織に薬物を注入する薬物注入具として用いることができる。

本発明に使用する発振素子は、導管の径と略同径、約1～10mmの円柱形又は中央に透孔を有する円筒形セラミック発振素子又は同形状に成形したソフトタイプのフィルム発振素子が好適に使用することができる。

なお、発振素子の中央に透孔を有する発振素子を使用する場合は、この透孔を注入薬物等の流入口としてもよく、また、体内液の排出口としてもよい。なお、排出口とする場合は、基部及び導管内に円筒状の隔壁を設け、中央路及び外周路の2室に分け、基部及び導管の中央路及び外周路を対応するように連接し、中央路を体内液の流通路とし、外周路を薬物等の流通路とする。そして、発振素子の透孔を導管の体内液の流通路に連接する。導管に、この発振素子と近接する部位に薬物等の流出孔を設ける。

中央に透孔を有しない円筒形の発振素子を使用する場合は、導管本体に、この発振素子と近接する部位に薬物等の流出孔を設ける必要がある。

上記の導管の先端に設けられた超音波発振素子は、本発明の注入具の基部に備えられた超音波発振機又は同発振機に接続されるコネクターと導線により接合されている。この導線は導管の部材中に埋めて保持してもよく、その内部表面に接着させて保持させてもよい。

〔作用〕

本発明は上記のように構成されているから、超音波を発振する素子が常に薬物等の標的部位に最も近い位置において振動を与えつつ薬物等が注入される。従って、標的部位の組織に対し、拡散，浸透が極めて良好に行われる。また、発振素子の超音波の強さの調節、超音波周波数の調節は、本発明の注入具に設置又は接続されている超音波発振機により適宜調節することができる。従って、その選択により限定部位の大きさを制御することができる。

〔実施例〕

次に本発明の薬物注入具の例を添付図面により説明する。

例1

第1図に示すように、中央部に薬物等の流通路5を貫通し、その開放部を薬物等の供給口6とした注入具基部1に超音波発振機8に接続するコネクター7を備え、この基部1の供給口6の反対側の先端に、直径1～10mmの薬物等の流通路4を形成した中空プラスチック製導管2を接合し、この導管2の先端に導管と適合する直径の高さ1～10mmの円筒形セラミック発振素子3を接合する。この円筒形セラミック発振素子3には、その中央部に直径0.5～9mmの透孔9を穿設してある。

セラミック発振素子3とコネクター7は導線10により接続する。そして、この導線10は導管2の内壁面又は壁内に保持する。

一方、コネクター7は超音波発振機8に接続する。

例2

本例は、例1の薬物注入具において、発振素子3に透孔を有しない場合である。

従って、発振素子3及び導管2の先端以外は例1と同様でる。

第2図は発振素子3及び導管2の先端部を表す。

第2図に示すように、セラミック発振素子3は透孔を有せず、導管の下部のセラミック発振素子3と接合する部位のやや上方に透孔11を設ける。

例3

第3図に示すように、注入具基部1内を隔壁12によって、中央路と外周路とに分け、中央路を体内液排出路13とし、外周路を薬物等の流通路5とする。そして、この各流通路の開放部を体内液排出口14及び薬物等の供給口6とした。この注入具基部1に超音波発振機8に接続するコネクター7を設け、体内液排出口14、薬物等の供給口6の反対側の先端に、基部と同様に導管の隔壁16によって中央路と外周路とに分け、中央路を導管2の体内液流通路15，外周路を薬物等の流通路4とする導管2を基部1の体内液流通路13及び薬物等の流通路5と導管2の体内液流通路15及び薬物等の流通路4が連結するように各通路を接合する。

導管2の他端に透孔9を設けた円筒形セラミック発振素子3の内周が導管2の体内液流通路15と、セラミック発振素子3の外周が導管2の外周とそれぞれ一致するように結合させ、導管2とセラミック発振素子3の結合部のやや上部の導管壁に透孔11を穿設し薬物等の流出口とする。

なお、セラミック発振素子3とコネクター7は導線10により接続する。そして、この導線10は導管2の内壁面に接着し保持する。

一方、コネクター7は超音波発振機8に接続する。

本品は、薬物等の注入と共に器官中の液状物を、同液中に浮遊する凝集物を超音波により砕砕，溶解させ外部に排出することができる。

（発明の効果）

本発明は薬物等の組織内への注入を超音波振動を与えつつ行うから、薬物等の拡散，浸透が著しく良好になり、例えば、心臓冠動脈の血栓症の治療に、本発明の薬物注入具を血栓近くまで入れ、溶解剤（ウロキナーゼ等）を注入すれば血栓溶解剤の溶解率は著しく増強され、血流再開までの時間も短縮され、臨床成績は改善される。

また、脳出血部の血腫の中に本発明の薬物注入具、特に実施例3の構造のものを使用すると、血栓溶解剤を注入すると同時に超音波照射により血腫を溶解して導管より吸入し外部に排出することができ、脳出血の治療適応が著しく広められる効果を有する。

4.図面の簡単な説明

第1図は本発明の実施例1の薬物注入具の断面図、第2図は同実施例2の導管と超音波振動素子の結合部分を示した斜視図、第3図は同実施例3の薬物注入具の断面図を示す。

1：薬物注入具基部　2：導管
3：超音波発振素子　4：導管の薬物等の流通路
5：基部の薬物等の流通路
6：薬物等の供給口　7：コネクター
8：超音波発振機　9：超音波発振素子の透孔
10：導線　11：導管の透孔
12：基部の隔壁　13：基部の体内液流通路
14：体内液排出口　15：導管の体内液流通路
16：導管の隔壁

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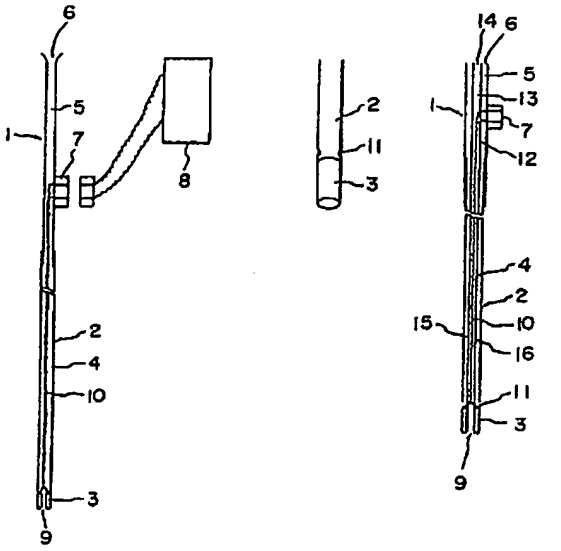
第１図　　第２図　　第３図



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(54) A drug injection device with an ultrasonic oscillation element attached

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1. Title of the Invention: A drug injection device with an ultrasonic oscillation element attached

2. Scope of Patent Claims

1. A drug injection device with an ultrasonic oscillation element attached, wherein the device is comprised by joining a conduit equipped with an ultrasonic oscillation element to the tip of a base equipped with a supply part for drugs, etc., as well as an ultrasonic oscillator or a connector that is connected to an ultrasonic oscillator, and this ultrasonic oscillation element and the ultrasonic oscillator are united electrically.

3. Detailed Explanation of the Invention

[Field of Industrial Application]

The present invention relates to a drug injection device that injects drugs from outside the body into the body through a catheter or drug injection conduit and imparts direct ultrasonic oscillations to the injection locus, and that improves the diffusion and penetration of the injected drugs, etc.

[Prior Art]

Among the methods for administering drugs from the outside for treatment, prevention, etc., of human diseases, there are methods for administering perorally and non-perorally by injection agents, peroral agents, suppositories, percutaneously administered agents, etc. Among the methods for injecting drugs directly into the body in particular, there are methods for injecting drugs to the target locus inside the body through local injection, arteriovenous injection, an intravascular catheter, etc.

In the event that drugs are injected directly into the body by these means, there are some injected drugs that diffuse in and penetrate into tissues with difficulty, and the chemical means have been the chief way for improving this situation to date.

The present inventors focused their attention on the fact that ultrasonic waves have previously been used to improve the diffusion and penetration of drugs during the administration of drugs by catheter, and invented a vascular irrigator that imparts oscillations by ultrasonic waves from a base that has been connected to a catheter (Japanese Public Patent Disclosure Bulletin No. S56-52071).

[Problems that the Invention Attempts to Solve]

In the above-mentioned prior art, in the case of drug injection by a catheter, in a method that employs ultrasonic waves to improve the diffusion to and penetration into indwelling matter in the blood vessels of the drugs that have been injected intravascularly by a catheter, since ultrasonic oscillator is located outside the body when ultrasonic waves are transmitted to the tip of the catheter, and is located in a position that is far from the tip of the catheter, there is an attenuation of the ultrasonic wave energy midway through the process, and it is difficult to achieve a full effect.

[Means for Solving the Problem]

The present inventors undertook further research into the methods for utilizing ultrasonic waves in order to improve the diffusion to and penetration into indwelling matter inside the blood vessels of drugs that have injected intravascularly at the time of injection of drugs , etc., by a catheter, and as a result thereof they discovered that by attaching an ultrasonic oscillation element to the tip of the part of the catheter inserted into the body, installing this oscillator on a base positioned outside the body, and joining the oscillation element electrically with this oscillator, the diffusion and penetration of drugs by local injection were carried out extremely well, and moreover by applying this not only to catheters but also to devices that are inserted inside the body, they completed the present invention, which provides a drug injection device with a wide range of uses.

This present invention is a drug injection device with an ultrasonic oscillation element attached, wherein the device is comprised by joining a conduit equipped with an ultrasonic oscillation element to the tip of a base equipped with a supply part for drugs, etc., as well as an ultrasonic oscillator or a connector that is connected to an ultrasonic oscillator, and this ultrasonic oscillation element and the ultrasonic oscillator are united electrically.

The drug injection device, which joins a conduit to the tip that is used in the present invention, possesses a distribution route for drugs, etc., in the center, as well as well as a base that possesses the open part of the former [i.e., the distribution route for drugs] as the

supply opening for drugs etc. and joins a conduit formed by a hollow slender tube mad of metal, rubber, plastic, etc., which possesses in its center a distribution route that corresponds to the distribution route of the drugs, etc., to and the tip of the opposite side of the supply opening of this base, and can be used as a drug injection device that injects drug directly into the tissues of the body, in addition to using it generally in the stomach, intestines, esophagus, trachea, blood vessels, etc.

A columnar (roughly the same diameter as the conduit, approximately 1 to 10 mm), or cylindrical ceramic oscillation element with a through hole in the center, or a film oscillation element of the soft type that is molded in the same shape, can be optimally used for the oscillation element used in the present invention.

In the event that a oscillation element with a through hole in the center of the oscillation element is used, this through hole may be the opening for the inflow of the injection drugs, etc., or it may be opening for the discharge of bodily fluids. In the event that it serves as the discharge opening, cylindrical partitions are provided inside the base and the conduit, these are separated into 2 chambers for the central routes and the peripheral routes, these are linked together such that the central routes and the peripheral routes of the base and conduit correspond, and the central route serves as the circulation route for bodily fluids and the peripheral route serves as the distribution route for drugs, etc. Then, the through hole of the oscillation element is linked together with the circulation route for bodily fluids of the conduit. On the conduit, an opening for the outflow of drugs is provided in a place that is in proximity to this oscillation element.

In the event that a cylindrical oscillation element that does not have a through hole in the center is used, it is necessary to provide a hole for the outflow of drugs, etc., in a place that is in proximity with this oscillation element, on the main body of the conduit.

The above-mentioned ultrasonic oscillation element provided on the tip of the conduit has been joined by a conductor with the ultrasonic oscillator or a connector that is connected with the same oscillator that is provided on the base of the injection device for the present invention. This conductor may be retained by embedding it inside a member of the conduit, or it may be retained making it adhere to the interior surface thereof

[Action]

Since the present invention is composed as described above, the drugs, etc., are injected while the element that oscillates the ultrasonic waves always imparts oscillations in the position nearest to the target locus of the drugs, etc. Therefore, the diffusion and penetration relative to the tissues of the target locus are performed extremely well. In addition, adjustment of the strength of the ultrasonic waves of the oscillation element and adjustment of the ultrasonic wave frequency can be performed at one's discretion by means of an ultrasonic oscillator that has been installed on or connected to the injection device for the present invention. Therefore, it is possible to control the size of a restricted locus based on this choice.

[Working Examples]

Next, an explanation of examples of the drug injection device for the present invention based on the appended figures is provided.

Example 1

As shown in Figure 1, the distribution route 5 for drugs, etc., passes completely through the center part, a connector 7 that connects to the ultrasonic oscillator 8 is provided on the base 1 of the injection device, which employs the open part of the above-mentioned

distribution route 5 as the supply opening 6 for drugs, etc., a hollow plastic conduit 2 that forms a distribution route for drugs, etc., with a diameter of 1 to 10 mm is joined to the tip of the opposite side of the supply opening 6 of this base 1, and a cylindrical ceramic oscillation element 3 with a diameter of 1 to 10 mm that conforms to that of the conduit is joined to the tip of this conduit 2. A through hole 9 with a diameter of 0.5 to 0.9 mm has been perforated in the center part in this cylindrical ceramic oscillation element 3.

The connector 7 is connected with the ceramic oscillation element 3 by a conductor 10. Then, this conductor 10 is maintained on the inner wall surface or inside the wall of the conduit 2.

On the other hand, the connector 7 is connected to the ultrasonic oscillator 8.

Example 2

This example involves a case where there is no through hole on the oscillation element 3, in the drug injection device in Example 1.

Therefore, it is the same as Example 1 except for the tips of the oscillation element 3 and the conduit 2.

Figure 2 shows the tips of the oscillation element 3 and the conduit 2.

A shown in Figure 2, the ceramic oscillation element 3 does not have a through hole, and a through hole 11 is provided slightly upwards of the region where the lower part of the conduit that joins with the ceramic oscillation element 3.

Example 3

As shown in Figure 3, owing to the partition 12 the interior of the base 1 of the injection device is divided into a central route and a peripheral route, and the central route serves as the route for discharging bodily fluids 13 and the peripheral route serves as the route for distributing drugs, etc. 5. Then, the open part of the respective distribution and circulation routes serves as the discharge opening for bodily fluids 14 and the supply opening for drugs, etc. 6. A connector 7 that is connected to the ultrasonic oscillator 8 is provided on the base 1 of this injection device, and each route is joined to the tip of the opposing side of the supply opening for drugs, etc., 6, such that it is divided into a central route and a peripheral route by means of a partition 16 of the conduit 2 in the same way as the base, and through the conduit 2, which employs the central route as the circulation route for bodily fluids 15 and the peripheral route as the distribution route for drugs, etc., 4, the circulation route for bodily fluids 13 and the distribution route for drugs, etc. 5 of the base 1, and the circulation route for bodily fluids 15 and the distribution route for drugs, etc. 4 of the conduit, are joined together.

The inner circuit of the cylindrical ceramic oscillation element 3 which provides a through hole 9 on the other end of the conduit 2 is united with the circulation route for bodily fluids 15 of the conduit 2, and the outer circuit of the ceramic oscillation element 3 is united with the outer circuit of the conduit 2, such that these respectively match, and a through hole 11 has been perforated in the conduit wall slightly above the point of union of the conduit 2 and the ceramic oscillation element 3, and this serves as the opening for outflow of drugs, etc.

The ceramic oscillation element 3 and the connector 7 are connected by a conductor 10. Then, this conductor 10 adheres to the inner wall surface of the conduit 2 and is retained there.

On the other hand, the connector 7 is connected to the ultrasonic oscillator 8.

This product can crush and dissolve the liquid like matter in the **[typo, meaning unclear, perhaps "tube"?]** along with the injection of the drugs, etc., and the condensed matter in the same fluid, with ultrasonic waves, and discharge this to the outside.

[Effects of the Invention]

Since in the case of the present invention injection of drugs, etc., into the tissues is carried out while ultrasonic oscillation is provided, the diffusion and penetration of the drugs, etc., improves markedly. For example, for treatment of thrombosis of the cardiac coronary artery, if the drug injection device for the present invention is inserted up to the vicinity of the thrombus, and a resolvent (urokinase) is injected, the dissolution rate of the thrombus resolvent is marked reinforced, and the time until the reopening of blood flow is also shortened, and the clinical results are improved.

In addition, if the drug injection device for this invention, and in particular a device with a structure like that in Working Example 3, is used in the hematoma of a cerebral hemorrhage, it is possible to dissolve the hematoma by ultrasonic irradiation at the same time as a thrombus resolvent is injected, and to take it in through the conduit and discharge it to the outside, and thus it has an effect whereby the therapeutic indications for cerebral hemorrhage are markedly widened.

4. Brief Description of the Figures

Figure 1 section of the drug injection device of the Working Example 1 for the present invention. Figure 2 is an oblique view that shows the union of the ultrasonic oscillation element with the conduit for Working Example 2 of the same. Figure 3 shows a section of the drug injection device of Working Example 3 for the same.

Key

1... Base of the drug injection device
2... Conduit
3... Ultrasonic oscillation element
4... Distribution route of the conduit for drugs, etc.
5... Distribution route of the base for drugs, etc.
6... Supply opening for drugs, etc.
7... Connector
8... Ultrasonic oscillator
9... Through hole of the ultrasonic oscillator
10... Conductor
11... Through hole of the conduit
12... Partition of the base
13... Route for circulation of bodily fluids of the base
14... Opening for discharge of bodily fluids
15... Route for circulation of bodily fluids of the conduit
16... Partition of the conduit

Patent Applicant: Toshiro Tachibana
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Figure 1

Figure 2

Figure 3

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